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<b>CLAIM LIMITATION</b>	<b>BASIS OF INVALIDITY CONTENTION</b>
1. A device for determining the result of an assay, comprising:	
a computation circuit, responsive to a signal representing the amount of an analyte or the rate of accumulation of an analyte, to:	
compare the signal to a first threshold;	
compare the signal to a second threshold, the second threshold being less than the first threshold;	
generate an output signal if the signal exceeds the first threshold or the signal is less than the second threshold, the output signal indicative of a first result if the signal exceeds the first threshold, or, alternatively, the output signal indicative of a second result if the signal is less than the second threshold; and	Claim 1 is invalid under 35 U.S.C. § 112 as indefinite because a person of ordinary skill in the art would not understand whether claim 1 requires a computation circuit that generates an output signal in both threshold conditions or either one of the conditions in order to infringe claim 1.
terminate the assay if the signal exceeds the first threshold or the signal is less than the second threshold.	Similarly, Claim 1 is invalid under 35 U.S.C. § 112 as indefinite because a person of ordinary skill in the art would not understand whether claim 1 requires a computation circuit that terminates the assay in both threshold conditions or either one of the conditions in order to infringe claim 1.
2. A device according to claim 1,	<i>See claim 1.</i>
wherein the first result is a positive result, and the second result is a negative result	
3. A device according to claim 1,	<i>See claim 1.</i>
wherein the computation	

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circuit is further responsive to the signal to repeat the comparisons and the conditional generation if the signal is between the first threshold and the second threshold.	
4. A device according to claim 1,	<i>See claim 1.</i>
further comprising an optical detection system for measuring the signal.	
5. A device according to claim 4,	<i>See claim 1.</i>
wherein the optical detection system comprises at least one light source and at least one photodetector.	
8. A device according to claim 1,	<i>See claim 1.</i>
further comprising a timer coupled to the computation circuit.	
10. A device according to claim 8,	<i>See claim 1.</i>
wherein the comparisons are performed within about 60 seconds of each other.	
11. A device according to claim 8,	<i>See claim 1.</i>
wherein the comparisons are performed at least about 30 seconds apart.	
12. A device according to claim 1,	<i>See claim 1.</i>
further comprising a housing enclosing the	

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computation circuit.	
13. A device according to claim 12,	<i>See claim 1.</i>
wherein the housing is no larger than about 12 cm long, about 2.5 cm wide, and about 2.2 cm tall.	
14. A device according to claim 12,	<i>See claim 1.</i>
further comprising at least one light source and at least one photodetector, and wherein:	
the housing defines an aperture for receiving at least a portion of a test strip inside the device, the assay strip having at least one zone, and	
the aperture, the light source, and the photodetector are positioned, sized and shaped so that, upon insertion of the test strip, light emitted from the light source is incident on the zone, and light emanating from the zone is incident on the photodetector, and wherein the photodetector generates a signal representing an amount of an analyte in the zone.	
15. A device according to claim 14,	<i>See claim 1.</i>
wherein the housing is no larger than about 12 cm long, about 2.5 cm wide, and about 2.2 cm tall.	

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18. A device accordingly to claim 1,	<i>See claim 1.</i>
further comprising at least one light source,	
at least one photodetector, and	
a test strip having at least one zone,	
wherein the light source, the photodetector, and the test strip are positioned, sized and shaped so that light emitted from the light source is incident on the zone, and	
light emanating from the zone is incident on the photodetector, and	
wherein the photodetector generates a signal representing an amount of an analyte in the zone.	
22. An assay result reading device for reading the result of an assay to detect the presence and/or amount of an analyte of interest and wherein the presence or absence, as appropriate, of the analyte of interest causes a reaction which leads to the accumulation of a signal in a time-dependent manner, the device comprising:	
means for determining the rate or amount of signal accumulation;	
means for comparing the determined rate or amount of signal accumulation with an upper threshold value;	
means for comparing the	

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determined rate or amount of signal accumulation with a lower threshold value; and	
means for declaring the result of the assay if the determined rate or amount of signal accumulation exceeds the upper threshold value or is below the lower threshold value or at such time when it is determined that the rate or amount of signal accumulation will not exceed or is not likely to exceed the lower threshold value before the assay has been completed.	<p>Claim 22 is invalid under 35 U.S.C. § 112 as indefinite because a person of ordinary skill in the art would not understand whether claim 22 requires means for declaring the result in both threshold conditions or either one of the conditions in order to infringe claim 22.</p> <p>Claim 22 is also invalid under 35 U.S.C. § 112 as indefinite and/or failing the written description and/or enablement requirement because a person of ordinary skill in the art would not understand how to interpret the claim. The specification discloses that “if after a certain period of time, the rate or amount of signal accumulation has not reached the lower threshold limit, it is considered that the signal will never reach the <b>upper</b> threshold even if the reaction were allowed to proceed to completion...” (col. 3, ll. 30-34). There is no support in the specification for the claimed means for declaring a result if the amount of signal accumulation will not or is not likely to exceed the <b>lower</b> threshold value.</p>
23. A method for determining a result of an assay, comprising:	
performing the assay to generate a signal representing the amount of an analyte or the rate of accumulation of an analyte;	
comparing the signal with a first threshold value before the assay reaches equilibrium;	<p>Claim 23 is invalid under 35 U.S.C. § 112 as indefinite and/or failing the written description and/or enablement requirement because a person of ordinary skill in the art would not understand what is meant by “equilibrium.”</p> <p>The specification describes that the assay devices of the prior art required the user to allow a preset time to elapse before displaying a result, and that the device of the invention can in certain circumstances determine a result “before an assay has completed.” (col. 2, ll. 25-28). In describing the use of a first threshold, the specification states “in the case of a high analyte concentration, the reading will cross the upper threshold at an earlier time” (col. 3, ll. 40-42) with no indication of what time this result is earlier</p>

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	<p>than. The specification then concludes that the disclosed invention “is able to display the results as soon as conveniently possible rather than necessarily wait for a preset time to elapse.” (col. 3, ll. 51-53). The specification further defines an end-point, <math>t_e</math>, at which the reader “considers the assay complete” but which, in reality, “may not necessarily be at completion of the reaction. Indeed, the end-point <math>t_e</math> will normally be considered to have been reached before the reaction is complete.” (col. 6, ll. 1-9) The end-point is then suggested to occur at a fixed time after commencement of the assay, much like the described prior art devices. (col. 6, ll. 10-15).</p> <p>The only reference to the term “equilibrium” in the specification is in column 9 where it states “an early result may be promptly declared after the reading has exceeded the lower threshold but the reader determines that the result will not exceed the upper threshold value before the reading has reached <b>equilibrium</b>” (col. 9, ll. 41-45) with no indication as to what time is actually referred to.</p> <p>Because a person of ordinary skill in the art would not understand how to interpret “equilibrium,” what claim 23 covers, and/or how to practice the method, claim 23 is invalid.</p>
comparing the signal with a second threshold value before the assay reaches equilibrium; and	<p>See discussion of “equilibrium” above.</p> <p>Claim 23 is further invalid under 35 U.S.C. § 112 as indefinite and/or failing the written description and/or enablement requirement because there is no ordered relationship between the claimed first and second thresholds. If the first threshold is set as lower than the second threshold, then the <i>declaring</i> step will encompass declaring a result for signal values between the two thresholds as well as those above and below. There is no support for such a situation in the specification, which expressly recites: “If however the determined rate or amount of signal accumulation is above the lower threshold but below the upper threshold, the assay must be continued.” (col. 5, ll. 63-65).</p>
declaring the result of the assay if the determined rate or amount of signal accumulation exceeds the first threshold value or is below the second threshold value.	<p>Claim 23 is invalid under 35 U.S.C. § 112 as indefinite because a person of ordinary skill in the art would not understand whether claim 23 requires declaring a result of the assay in both threshold conditions or either one of the conditions in order to infringe claim 23.</p>

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24. A method of declaring the result or outcome of an assay to detect the presence and/or amount of an analyte of interest, the method comprising:	
performing the assay so as to cause the reaction which leads to the accumulation of a signal in a time-dependent manner;	
determining, before the reaction has reached equilibrium, the rate or amount of signal accumulation;	<p>Claim 24 is invalid under 35 U.S.C. § 112 as indefinite and/or failing the written description and/or enablement requirement because a person of ordinary skill in the art would not understand what is meant by “equilibrium.”</p> <p>The specification describes that the assay devices of the prior art required the user to allow a preset time to elapse before displaying a result, and that the device of the invention can in certain circumstances determine a result “before an assay has completed.” Col. 2, ll. 25-28. In describing the use of a first threshold, the specification states “in the case of a high analyte concentration, the reading will cross the upper threshold at an earlier time” (col. 3, ll. 40-42) with no indication of what time this result is earlier than. The specification then concludes that the disclosed invention “is able to display the results as soon as conveniently possible rather than necessarily wait for a preset time to elapse.” (col. 3, ll. 51-53). The specification further defines an end-point, <math>t_e</math>, at which the reader “considers the assay complete” but which, in reality, “may not necessarily be at completion of the reaction. Indeed, the end-point <math>t_e</math> will normally be considered to have been reached before the reaction is complete.” (col. 6, ll. 1-9) The end-point is then suggested to occur at a fixed time after commencement of the assay, much like the described prior art devices. (col. 6, ll. 10-15).</p> <p>The only reference to the term “equilibrium” in the specification is in column 9 where it states “an early result may be promptly declared after the reading has exceeded the lower threshold but the reader determines that the result will not exceed the upper threshold value before the reading has reached <b>equilibrium</b>” (col. 9, ll. 41-45) with no indication as to what time is actually referred to.</p>

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	Because a person of ordinary skill in the art would not understand how to interpret “equilibrium,” what claim 24 covers, and/or how to practice the method, claim 24 is invalid.
comparing the determined rate or amount with an upper and a lower threshold value; and	
declaring the result or outcome of the assay if the determined rate or amount of signal accumulation exceeds the upper threshold value or is below the lower threshold value or at such time when it is determined that the rate or amount of signal accumulation will not exceed or is not likely to exceed the lower threshold value before the assay has been completed.	<p>Claim 24 is invalid under 35 U.S.C. § 112 as indefinite because a person of ordinary skill in the art would not understand whether claim 24 requires declaring a result of the assay in both threshold conditions or either one of the conditions in order to infringe claim 24.</p> <p>Claim 24 is also invalid under 35 U.S.C. § 112 as indefinite and/or failing the written description and/or enablement requirement because a person of ordinary skill in the art would not understand how to interpret the claim. The specification discloses that “if after a certain period of time, the rate or amount of signal accumulation has not reached the lower threshold limit, it is considered that the signal will never reach the <b>upper</b> threshold even if the reaction were allowed to proceed to completion...” (col. 3, ll. 30-34). There is no support in the specification for the claimed means for declaring a result if the amount of signal accumulation will not or is not likely to exceed the <b>lower</b> threshold value.</p>
27. A method comprising:	
performing an assay;	
before the assay has reached equilibrium, generating a signal representing the amount of an analyte or the rate of accumulation of an analyte;	<p>Claim 27 is invalid under 35 U.S.C. § 112 as indefinite and/or failing the written description and/or enablement requirement because a person of ordinary skill in the art would not understand what is meant by “equilibrium.”</p> <p>The specification describes that the assay devices of the prior art required the user to allow a preset time to elapse before displaying a result, and that the device of the invention can in certain circumstances determine a result “before an assay has completed.” Col. 2, ll. 25-28. In describing the use of a first threshold, the specification states “in the case of a high analyte concentration, the reading will cross the upper threshold at an earlier time” (col. 3, ll. 40-42) with no indication of what time this result is earlier than. The specification then concludes that the disclosed invention “is able to display the results as soon as conveniently possible rather than necessarily wait for a preset time to elapse.”</p>



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	<p>(col. 3, ll. 51-53). The specification further defines an end-point, <math>t_e</math>, at which the reader “considers the assay complete” but which, in reality, “may not necessarily be at completion of the reaction. Indeed, the end-point <math>t_e</math> will normally be considered to have been reached before the reaction is complete.” (col. 6, ll. 1-9) The end-point is then suggested to occur at a fixed time after commencement of the assay, much like the described prior art devices. (col. 6, ll. 10-15).</p> <p>The only reference to the term “equilibrium” in the specification is in column 9 where it states “an early result may be promptly declared after the reading has exceeded the lower threshold but the reader determines that the result will not exceed the upper threshold value before the reading has reached <b>equilibrium</b>” (col. 9, ll. 41-45) with no indication as to what time is actually referred to.</p> <p>Because a person of ordinary skill in the art would not understand how to interpret “equilibrium,” what claim 27 covers, and/or how to practice the method, claim 27 is invalid.</p>
comparing the signal with a first threshold value;	
comparing the signal with a second threshold value; and	<p>Claim 27 is invalid under 35 U.S.C. § 112 as indefinite and/or failing the written description and/or enablement requirement because there is no ordered relationship between the claimed first and second thresholds. If the first threshold is set as lower than the second threshold, then the <i>declaring</i> step will encompass declaring a result for signal values between the two thresholds as well as those above and below. There is no support for such a situation in the specification, which expressly recites: “If however the determined rate or amount of signal accumulation is above the lower threshold but below the upper threshold, the assay must be continued.” (col. 5, ll. 63-65).</p>
declaring a result of the assay if the determined rate or amount of signal accumulation exceeds the first threshold value or is below the second threshold value.	<p>Claim 27 is invalid under 35 U.S.C. § 112 as indefinite because a person of ordinary skill in the art would not understand whether claim 27 requires declaring a result of the assay in both threshold conditions or either one of the conditions in order to infringe claim 27.</p>